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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/810,988	SCHEUCH ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25,28-30,35-38 and 42-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25,28-30,35-38 and 42-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/15/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment and declarations filed August 15, 2008. As directed by the amendment, claims 46 and 47 have been amended and claims 1-21, 26-27, 31-34, and 39-41 are cancelled. Thus, claims 22-25, 28-30, 35-38, and 42-47 are pending in this application.

Claim Objections

2. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim. In the instant case, claim 25 is the first independent claim with claims 22-24, 28-30, 35-38, 42 and 45 depending therefrom.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 22-25, 28-30 and 35-38, and 42-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The original specification does not provide support for the limitation of "controlling an air flow through the inhalation device using the inhalation device during the controlled inhalation" as claimed in claims 25, 43 and 44.

The original specification does not provide support for the limitation of controlling the air flow velocity as claimed in claim 37.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 24, 25, 28, 38, and 42-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Brooker (6,269,810).

Brooker discloses a method for administering a controlled inhalation of an aerosol for a patient during breathing maneuvers including inputting into an inhalation device a plurality of parameters which include both aerosol and patient specific parameters, individually adjusting the inhalation device to the patient by adapting a dosage of an aerosol on the basis for the previous parameters by evaluating the parameters and adjusting a flow or tidal volume of the device based on the aerosol

parameters such that an optimal dose of the aerosol is delivered to a specific location in the lungs during controlled inhalation and controlling the air flow through the device using the device during controlled inhalation. See col. 6 lines 12-51; col. 7 lines 19-48, col. 12 lines 24-42 and col. 13 line 40-col. 14 line 20. The tidal volume and capacity are previously determined by pulmonary tests. The data used to program the device includes aerosol parameters, device parameters and patient specific parameters-col. 7 lines 32-48.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker (6,269,810),as applied to claim 25 above, in view of Servidio, et al (5,598,838).

Brooker discloses the invention as claimed with the exception of the modem. Servidio discloses that it was known to upload or download data to a respiratory device via a modem. It would have been obvious to have provided the system of Brooker with a modem in order to be able to provide the device with data remotely.

9. Claims 22, 29, 30, 35-37 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker (6,269,810) in view of Willemot (5,560,353).

Brooker discloses the method as claimed with the exception of the use of a smart card or memory card to program the inhalation device. Willemot discloses that it was

known to use such memory cards as input devices for inhalation devices. It would have been obvious to have had a physician program patient and drug data, for example, onto a memory card for placement into a reading device connected to the control means of the inhalation device, as this allows for safe transmission and a proper treatment regimen for each specific patient. Providing the device the capability to read and alter the controls of the inhalation device using the data from the card would have increased the effectiveness and adaptability of the device to facilitate the device in its use by different patients. One of skill in the art would have had every reason to expect success in achieving the predictable result of making the system more user friendly and more adaptable to different patients and drug treatment regimens.

10. Claims 24-25, 28, 38 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989), which is the English equivalent of (WO98/52633) in view of Brooker (6,269,810).

Brand discloses a method for administering a controlled inhalation of an aerosol for a patient during breathing maneuvers; however, the controlling of the air flow through the device during the controlled inhalation is not disclosed. The hardware of the system seems to be similar to that of the applicant with the exception of the modifications involving the controlling and adjustability with respect to the individual patient. However, Brooker discloses inputting into an inhalation device a plurality of parameters which include both aerosol and patient specific parameters, individually adjusting the inhalation device to the patient by adapting a dosage of an aerosol on the basis for the previous parameters by evaluating the parameters and adjusting a flow or

tidal volume of the device based on the aerosol parameters such that an optimal dose of the aerosol is delivered to a specific location in the lungs during controlled inhalation and controlling the air flow through the device using the device during controlled inhalation.

It would have been obvious to have modified the method taught by Brand to include the hardware and software changes taught by Brooker which are necessary to allow for the inputting of aerosol and patient specific parameters into the inhalation device to cause it to alter the air flow through the device depending on the patients requirements, as this would allow for specific tailoring of the accurate delivery of the aerosol medication to the particular patient's needs. This would greatly increase the accuracy of the correct dosing to any particular patient.

Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989), which is the English equivalent of (WO98/52633) in view of Brooker (6,269,810), and further in view of Servidio, et al. (5,598,838).

Brand as modified by Brooker makes obvious the invention as claimed with the exception of the modem. Servidio discloses that it was known to upload or download data to a respiratory device via a modem. It would have been obvious to have provided the system of Brand and Brooker with a modem in order to be able to provide the device with data remotely.

Claims 22, 29, 30, 35, 36, 37 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989), which is the English equivalent of (WO98/52633) in view of Brooker (6,269,810), and further in view of Willemot-5560353.

Brand as modified by Brooker makes obvious the method as claimed with the exception of the use of a smart card or memory card to program the inhalation device. Willemot discloses that it was known to use such memory cards as input devices for inhalation devices. It would have been obvious to have had a physician program patient and drug data, for example, onto a memory card for placement into a reading device connected to the control means of the inhalation device, as this allows for safe transmission and a proper treatment regimen for each specific patient. Providing the device the capability to read and alter the controls of the inhalation device using the data from the card would have increased the effectiveness and adaptability of the device to facilitate the device in its use by different patients. One of skill in the art would have had every reason to expect success in achieving the predictable result of making the system more user friendly and more adaptable to different patients and drug treatment regimens.

Response to Arguments

Applicant's arguments with respect to the 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement have been fully considered. However, applicant failed to provide the statement required by 37 CFR 1.57(f) which that such an amendment must be accompanied by a statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter.

Moreover, the amendment to the specification merely provides that “the inhalator controls air flow velocity there through during inhalation by the patient“, not “controlling

an air flow through the inhalation device **using the inhalation device during the controlled inhalation**" as claimed in claims 25, 43 and 44. (Emphasis added).

Applicant's arguments to the 35 USC 102(e) rejection of claims 24, 25, 28, 38, and 42-44 as being anticipated by Brooker have not been taken well. Applicant argues that Brooker does not disclose individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters has not been taken well because Booker adjusts the aerosol pulse and since the adjusted pulse would make up a portion of the respiratory flow or the tidal volume, and given that tidal volume is the lung volume representing the normal volume of air displaced between normal inhalation and exhalation when extra effort is not applied, the adjustment of the pulse would adjust the respiratory flow or tidal volume (at least to some extent).

Applicant's arguments to the 35 USC 103(a) rejection of claim 23 as being unpatentable over Brooker (6,269,810) in view of Servidio, et al (5,598,838) have not been taken well. Applicant argues that Brooker lacks the individually adjusting an inhalation device, as described above and Servidio does not teach or suggest what Brooker lacks. However, the examiner respectfully disagrees. As discussed above, Brooker teaches adjusting the respiratory flow or tidal volume by adjusting the aerosol pulse and Servidio was used to teach that it was known to upload or download data to a respiratory device via a modem and that It would have been obvious to have provided the system of Brooker with a modem in order to be able to provide the device with data remotely.

Applicant's arguments to the 35 USC 103(a) rejection of claims 22, 29, 30, 35-37 and 45-47 under 35 U.S.C. 103(a) as being unpatentable over Brooker (6,269,810) in view of Willemot (5,560,353) have not been taken well.

Applicant argues that Brooker lacks the individually adjusting an inhalation device, as described above and Willemot does not teach or suggest what Brooker lacks. However, the examiner respectfully disagrees. As discussed above, Brooker teaches adjusting the respiratory flow or tidal volume by adjusting the aerosol pulse and Willemot was used for the use of a smart card or memory card as input devices for inhalation devices to program the inhalation device.

Applicant's arguments to the 35 USC 103(a) rejection of claims 24-25, 28, 38 and 42-44 under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989), which is the English equivalent of (WO98/52633) in view of Brooker (6,269,810) have not been taken well.

Applicant argues that Brand lacks the individually adjusting an inhalation device, as described above and Brooker does not teach or suggest what Brand lacks. However, the examiner respectfully disagrees. As discussed above, Brand discloses a method for administering a controlled inhalation of an aerosol for a patient during breathing maneuvers and Brooker was used to teach adjusting the respiratory flow or tidal volume by adjusting the aerosol pulse.

Applicant's arguments to the 35 USC 103(a) rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989), which is the English

equivalent of (WO98/52633) in view of Brooker (6,269,810) and further in view of Servidio, et al (5,598,838) have not been taken well.

Applicant argues that Servidio does not provide what Brand and Brooker lack, however, the examiner respectfully disagrees. Brand discloses a method for administering a controlled inhalation of an aerosol for a patient during breathing maneuvers and Brooker was used to teach adjusting the respiratory flow or tidal volume by adjusting the aerosol pulse and Servidio was used to teach that it was known to upload or download data to a respiratory device via a modem and that It would have been obvious to have provided the system of the combined references with a modem in order to be able to provide the device with data remotely.

Applicant's arguments to the 35 USC 103(a) rejection of claims 22, 29, 30, 35, 36, 37 and 45-47 under 35 U.S.C. 103(a) as being unpatentable over Brand (6,606,989), which is the English equivalent of (WO98/52633) in view of Brooker (6,269,810), and further in view of Willemot-5560353 have not been taken well.

Applicant argues that Willemot does not provide what Brand and Brooker lacks. However, the examiner respectfully disagrees. As discussed above, Brand discloses a method for administering a controlled inhalation of an aerosol for a patient during breathing maneuvers and Brooker was used to teach adjusting the respiratory flow or tidal volume by adjusting the aerosol pulse and Willemot was used for the use of a smart card or memory card as input devices for inhalation devices to program the inhalation device.

Response to Declarations

11. The declarations of Bernhard Muellinger, William Zimlich, Jr., and Peter Brand under 37 CFR 1.132 filed August 15, 2008 are insufficient to overcome the rejection of claim22-25, 28-30, 35-38, and 42-47 as set forth in the last Office action because:

12. The declaration filed by Bernhard Muellinger refers to the system and method described in the above referenced application; however it fails to give the claims their broadest reasonable interpretation and appear to read limitations into the claims.

For instance, Bernhard Muellinger's declaration refers to Bookers lack of a respirator or the like; however, none of the claims rejected by Booker require a respirator. Bernhard Muellinger's declaration refers to Bookers lack of a metered volume of inhaled breath, another limitation not required by any of the rejected claims.

Bernhard Muellinger's declaration describes to how Booker adjusts the aerosol pulse, not the respiratory flow or tidal volume. However, since the adjusted pulse would make up a portion of the respiratory flow or the tidal volume, and given that tidal volume is the lung volume representing the normal volume of air displaced between normal inhalation and exhalation when extra effort is not applied, the adjustment of the pulse would adjust the respiratory flow or tidal volume (at least to some extent).

The examiner respectfully agrees with Bernhard Muellinger's declaration that Brand does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters and Brand does not teach or suggest adjusting flow rate or tidal volume based on inhalation parameters. However, this rejection was based on a combination of Brand with Booker and Brooker discloses inputting into an inhalation

device a plurality of parameters which include both aerosol and patient specific parameters, individually adjusting the inhalation device to the patient by adapting a dosage of an aerosol on the basis for the previous parameters by evaluating the parameters and adjusting a flow or tidal volume of the device based on the aerosol parameters such that an optimal dose of the aerosol is delivered to a specific location in the lungs during controlled inhalation and controlling the air flow through the device using the device during controlled inhalation.

The examiner agrees with Bernhard Muellinger's declaration that Servidio does not teach or suggest individually adjusting an inhalation device to a patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters and that Servidio does not teach or suggest adjusting flow rate or tidal volume based on the inhalation parameters. Instead, Servidio teaches a pressure support device to provide air under positive pressure. However, Servidio was used to teach that it was known to upload or download data to a respiratory device via a modem and that It would have been obvious to have provided the system of Brooker with a modem in order to be able to provide the device with data remotely.

The examiner agrees with Bernhard Muellinger's declaration that Willemot does not teach or suggest individually adjusting an inhalation device to a patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters and Willemot does not teach or suggest adjusting flow rate or tidal volume based on inhalation parameters. However, Willemot was used for the use of a smart card or memory card as input devices for inhalation devices to program the inhalation device.

13. The declaration filed by William C. Zimlich, Jr., refers to the system and method described in the above referenced application; however it fails to give the claims their broadest reasonable interpretation and appear to read limitations into the claims.

For instance, the declaration by William C. Zimlich, Jr.., describes how Brooker does not teach or suggest a variable inhalation volume or variable flow rate. The respiratory flow rate is not claimed, as the claims require adjusting the respiratory flow (generally). William C. Zimlich, Jr., declaration that "At the time, those skilled in the art were concerned with how much medicament was being delivered into the mouth, not where it went within the respiratory tract system" has not been taken well. It has been well known in the art (See: Booker), to aerosolize particles for respiratory tract to obtain a benefit that largely outweighs placing a tablet in the mouth of a user; particularly for the treatment of respiratory disorders.

The declaration by William C. Zimlich, Jr., also refers to the particle deposition within the lungs; however, the claims only require the "aerosol is applied to a desired section of the lung of a patient" and this reads on any portion of the lung. However, it appears William C. Zimlich, Jr., has read this as a specific portion of the respiratory tract.

14. The declaration filed by Peter Brand which essentially describes the Brand invention and offers and provides a reference (Giraud) to show that misuse of pressurized metered-dose inhalers is mainly due to poor coordination and that controlled aerosol delivery to the lungs can be guaranteed when inhalation parameters are inputted into the inhalation device.

The declaration filed by Peter Brand describes how Brand does not teach or suggest individually adjusting an inhalation device to the patient to be treated by adapting a dosage of at least one aerosol on the basis of the inhalation parameters, adjusting flow rate or tidal volume based on inhalation parameters, or controlling an air flow through an inhalation device using the inhalation device during the controlled inhalation.

However, this rejection was based on a combination of Brand with Booker and Brooker discloses inputting into an inhalation device a plurality of parameters which include both aerosol and patient specific parameters, individually adjusting the inhalation device to the patient by adapting a dosage of an aerosol on the basis for the previous parameters by evaluating the parameters and adjusting a flow or tidal volume of the device based on the aerosol parameters such that an optimal dose of the aerosol is delivered to a specific location in the lungs during controlled inhalation and controlling the air flow through the device using the device during controlled inhalation.

Thus, the declaration of Peter Brand provides arguments against the reference individually, however one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Loedding et al. (5,156,776); Evans (5,161,524); Ryder

(5,415,161); Denyer et al (6,116,223); Denyer et al (5,842,468); and Halpern et al. (5,687,717) which are drawn to aerosol and computer controlled patient delivery and monitoring systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is 571-272-5559. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771